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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/698,903	10/27/2000	Brigitte Weston	514412-2020.1	8217
20999	7590	12/17/2003	EXAMINER	
FROMMER LAWRENCE & HAUG 745 FIFTH AVENUE- 10TH FL. NEW YORK, NY 10151			KUBELIK, ANNE R	
		ART UNIT	PAPER NUMBER	
		1638		

DATE MAILED: 12/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b>	Application No.	Applicant(s)
	09/698,903	WESTON ET AL.
	Examiner	Art Unit
	Anne R. Kubelik	1638

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 06 November 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a)  The period for reply expires 4 months from the mailing date of the final rejection.
- b)  The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.  A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2.  The proposed amendment(s) will not be entered because:
  - (a)  they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b)  they raise the issue of new matter (see Note below);
  - (c)  they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d)  they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3.  Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4.  Newly proposed or amended claim(s) \_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5.  The a) affidavit, b) exhibit, or c) request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6.  The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7.  For purposes of Appeal, the proposed amendment(s) a) will not be entered or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 24-26, 30-32, 34-42.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8.  The drawing correction filed on \_\_\_\_ is a) approved or b) disapproved by the Examiner.

9.  Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.

10.  Other: \_\_\_\_\_.

## Continuation of 2. NOTE:

New issues: 112 2<sup>nd</sup>: Claim 24, line 11, claims 34-35, line 8, and claim 36, line 10, lack antecedent basis for the limitation "the foreign DNA".

New matter: The amendment of the paragraph beginning pg 16, line 15, of the specification is new matter. There is no support in the originally filed specification for recitation of oligonucleotides being at least 16 or 20-24 nucleotides long.

With respect to newly amended claims 24, 26, 30, and 34-36, there is no support in the originally filed specification for recitation of oligonucleotides comprising at least any 16 consecutive nucleotides of bases 1-234 of SEQ ID NO:8, bases 194-416 of SEQ ID NO:10, or of SEQ ID NO:1.

With respect to newly filed claims 37-42, there is no support for recitation of probes or primers comprising any 20-24 nucleotides of bases 1-234 of SEQ ID NO:8, bases 194-416 of SEQ ID NO:10, or of SEQ ID NO:1.

## Continuation of 5. does NOT place the application in condition for allowance because:

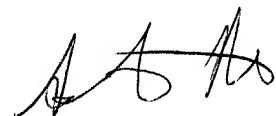
112, 1<sup>st</sup>, enablement: Applicant urges that the claims have been amended to recite that the PCR probes or primers comprise at least 16 or 20-24 nucleotides from the foreign DNA, from the 5' flanking region or the 3' flanking region and that specific oligonucleotides are exemplified in the specification. Applicant urges that the development of PCR primers is routine and predictable. This is not found persuasive. The specification does not teach probes and primers within the full scope of the claims and does not teach 16 oligonucleotide primers at all.

112, 1<sup>st</sup>, written description: applicant urges that they need not have physical possession of each and every primer and probe encompassed by the claims, and that the structural features that distinguish the probes and primers from other nucleic acids are clearly delimited by the requirement that they be derived from SEQ ID NOs: 1, 8 or 10. Applicant urges that a representative number of cDNAs falling within the genus have been disclosed. This is not found persuasive. The specification does not describe 16 oligonucleotide probe and primers at all and only describes a couple that are 20-24 nucleotides long and that correspond to the recited bases of SEQ ID NOs: 8 and 10. Thus, the full scope of the primers are not described. The rejection is not directed to cDNAs.

112, 2<sup>nd</sup>: Applicant urges that the steps of using a PCR are merely clearly defined. This is not found persuasive because recitation of probes and primers does not define what one must do to practice the invention. Claim 35 remains similarly indefinite.

The other 112, 2<sup>nd</sup> rejections would have been obviated by the amendments.

Double patenting. The terminal disclaimer filed on 6 November 2003 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 6,509,516 has been reviewed and is accepted. The terminal disclaimer has been recorded.



ASHWIN D. MEHTA, PH.D  
PATENT EXAMINER